Amendments to the Drawings:

The attached sheet of drawings includes changes to Fig. 13. This sheet, which includes Figs. 8, and 10-15, replaces the original sheet including Fig. 8 and 10-15. In Figure 13, the element previously identified as 14 has been amended to 310.

Attachment: Replacement Sheet

Annotated Sheet Showing Changes

REMARKS

Status of the Claims:

Claims 25-62 are pending in this application and claims 31, 44-49, 61 and 62 are withdrawn. Applicants have amended the specification and Fig. 13 to correct typographical errors. In addition, Applicants have cancelled claims 25 and 59-60, amended claims 26-30, 32-43 and 50 and 58, and added new claims 63-67.

New claims 63, 64, 66 and 67 find support throughout the application as filed. For example, support for new claims 63 and 67 can be found in claims 1 and 15, on page 12, lines 14-27, page 15, lines 8-17, page 23, lines 3-12 of the specification, and Figures 6, 7 and 9 as originally filed. Support for new claim 64 can, for example, be found in claim 12 as originally filed. In addition, support for new claim 66 can, for example, be found on page 37, lines 2-5 of the specification as originally filed. Specifically, the specification as originally filed describe at page 37, lines 2-5 that "[a]romatic diisocyanates include p-phenylene diisocyanate, 4,4'-diphenylmethane diisocyanate ("4,4'-MDI"), 2,4'-diphenylmethane diisocyanate ("2,4'-MDI"), 2,4-toluene diisocyanate ("2,4-TDI"), 2,6-toluene diisocyanate("2,6-TDI"), m-tetramethylxylene diisocyanate, and mixtures thereof."

Support for the amendment to claim 36 for "a flexible material" is supported throughout the specification as originally filed. For example, page 26, lines 20-22 of the specification recites "one or more flexible, possibly sheet-like, elastomeric matrices."

The amendments to claim 42 are also supported throughout the specification as filed. In particular, page 20, line 22 to page 22 line 13 of the specification and Figures 22-24 as originally filed provide support for "an elongated configuration" for the second configuration. Support for the amendments to claims 51 and 53 and new claim 65 are found throughout the

application as filed. Specifically, page 30, lines 16 to 21 of the specification as originally filed provide the claimed pores sizes in μm units.

Furthermore, the amendments to claim 55 are supported throughout the specification as originally filed. For example, page 36, lines 4-6 and page 38, line 29 to page 39, line 10 of the specification as originally filed provide support for the specific elastomers recited by amended claim 55.

Support for the amendments to claims 29, 30, 32, 38, 39 and 41 for a "vascular malformation" are found throughout the application as filed. For example, support for these amendments may be found on page 23, lines 3-5 of the specification, which recites "...vascular malformations, such as for aneurysm control, arterio venous malfunction, arterial embolization or other vascular abnormalities, or as substrates for pharmaceutically-active agent, e.g., for drug delivery."

The amendments to claims 26-28, 30, 32, 35, 36, 50-54 and 56-58 for a "polymeric matrix" find support throughout the application as filed. For example, page 13, lines 3-6 of the specification discloses that "[a] preferred foam is a compressible, lightweight material, chosen for ability to expand..." and page 15, lines 8-17 of the specification describes "...employing a reticulated biodurable elastomeric matrix, a polymeric foam, or a comparably cleavable material, as the primary structural material of the implant."

The remaining amendments to the claims are made to merely simplify language and correct dependencies and are therefore considered purely cosmetic. Applicants respectfully submit that no new matter has been added and request entry of these new claims.

Claims 25-30, 32-43 and 50-60 stand rejected. Claim 55 is rejected under 35 U.S.C. §112, ¶2 as indefinite for allegedly failing to particularly point out and distinctly claim

the subject matter which the Applicants regard as the invention. Claims 25-30, 32-43, 50 and 58-60 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,904,703 to Gilson ("Gilson"). Claims 51-53 are rejected under 35 U.S.C. §103 as being unpatentable over Gilson as applied to claim 25 and further in view of U.S. Patent Application Publication No. 2002-001884 by Thomson ("Thomson"). Claims 54 and 55 are rejected under 35 U.S.C. §103 as being unpatentable over Gilson as applied to claim 25 and further in view of U.S. Patent No. 6,784,273 to Spaans et al. ("Spaans").

In view of the above amendments and following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Drawings:

The Examiner objects to the drawings as allegedly failing to comply with 37 C.F.R. §1.84(p)(5) because they do not include reference signs 16 and 21 mentioned in the description. Applicants have amended the specification to address the Examiner's concerns. Accordingly, Applicants respectfully request withdrawal of this objection.

Specification:

The Examiner objects to the specification because the "Brief Description of the Drawings" section is allegedly "replete with errors." Applicants respectfully disagree with this characterization, but have amended the specification to address the Examiner's concerns. In view of the foregoing amendments to the specification, Applicants respectfully request withdrawal of this objection.

Response to Indefiniteness Rejection Under 35 U.S.C. §112, ¶2:

The Examiner rejects claim 55 for allegedly failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Claim 55, as amended, depends from claim 27 and recites a "reticulated biodurable elastomeric matrix." In view of the foregoing amendments, Applicants respectfully request withdrawal of this ground of rejection.

Response to Anticipation Rejection Under 35 U.S.C. §102(b):

Claims 25-30, 32-43, 50 and 58-60 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,904,703 to Gilson ("Gilson"). Applicants have canceled claim 25 and added new claims 63-27 and respectfully traverse this ground of rejections.

The Examiner contends that Gilson describes implants that provide support to a portion of the internal wall. (See Office Action, p. 4). The citation provided by the Examiner describes that the device's "structural integrity and stiffness properties will ensure that once deployed, it will remain in place postoperatively." (Gilson, col. 4, line 67 to col. 5, line 2). The mechanism for securing the device in place is clarified by the disclosure that "[p]referably, the cross-sectional area of the neck is the same or greater than the cross-sectional area of the defect opening for a snug fit or interference fit centering the device in the opening." (Gilson, col. 5, lines 45-48).

There is no teaching or suggestion in Gilson that the device can provide physical support to the internal wall of the abnormal physiological formation as recited in new, independent claim 63. Rather, the Gilson device pushes against the edges of the tissue walls of a defect opening and is held in place by a counteracting force exerted by the tissue walls of the

defect opening. In addition, the Gilson device may include disks mounted in a tissue wall for occluding a defect opening. (Gilson, col. 5, lines 39-40). When deployed, the disks "closely follow the contours of the walls for a tight and accurate fit." (Gilson, col. 5, lines 42-45.). The "walls" are those of the defect opening, not the internal walls of the aneurysm or other vascular malformation. One skilled in the art would understand that a defect opening, as described by and illustrated in Figure 6 of the Gilson reference, is discontinuous and cannot enclose an internal volume. Further, as can be seen in Figure 6, the Gilson device having a plurality of disks is substantially flat and would not conform to the shape of an internal wall of a vascular malformation. Therefore, Gilson does not teach or suggest a configuration that is at least in part fitted to a shape of the internal wall for providing physical support to the internal wall of the vascular malformation as recited by Applicant's independent claim 63. For at least the foregoing reasons, Gilson cannot anticipate independent claim 63 nor the claims dependent therefrom.

Similarly, independent claim 67 also requires a configuration at least in part fitted to a shape of the internal wall for providing support for at least a portion of the internal wall of the vascular malformation. Because Gilson does not teach or suggest a device for supporting the internal wall of a vascular malformation, claim 67 also cannot be anticipated.

Furthermore, the Examiner contends that "Gilson discloses a porous matrix (see figures 1a-3) and therefore also is interpreted to comprise a reticulated elastomeric matrix." (Office Action, pp.4-5). Applicants respectfully disagree. Applicants' specification provides that a reticulated matrix possesses a microstructure or interior structure comprising "inter-connected open pores bounded by configuration of the struts and intersections that constitute the solid structure." (Specification, page 27, lines 12-16). As shown in Figure 1b reproduced below,

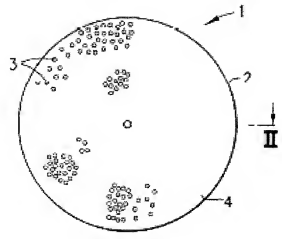

FIG. 1b

Gilson describes a porous matrix having individualized pores, but does not teach or suggest a reticulated matrix comprising inter-connected open pores bounded by configuration of the struts and intersections that constitute the solid structure. Therefore, Applicants respectfully submit that Gilson cannot anticipate claims 26, 27, 34, 36, 37, 52, 55 and 65, which recite a reticulate matrix.

Accordingly, independent claims 63 and 67 and the claims dependent therefrom are not anticipated by Gilson. For at least the foregoing reasons, Applicants respectfully request withdrawal of all §102(b) rejections over Gilson.

Response to Obviousness Rejection Under 35 U.S.C. §103:

Claims 51-53 are rejected under 35 U.S.C. §103 as being unpatentable over Gilson as applied to claim 25 and further in view of U.S. Patent Application Publication No. 2002-001884 by Thomson ("Thomson"). Claims 54 and 55 are rejected under 35 U.S.C. §103 as being unpatentable over Gilson as applied to claim 25 and further in view of U.S. Patent No. 6,784,273 to Spaans et al. ("Spaans"). Applicants respectfully traverse this ground of rejections.

For at least the reasons discussed above, Gilson fails to teach or suggest all of the claim elements of Applicants' amended claims. As demonstrated below, the secondary references cited by the Examiner, Thomson and Spaans, do not cure the deficiencies of Gilson.

Thomson discloses a foam composite made up of a scaffold of an open cell hydrophobic material having plurality of surfaces defining a plurality of pores, and a coating of a substantially hydrophilic foam material disposed upon the surfaces of the hydrophobic foam. Thomson does not, however, teach or suggest a device for treating a vascular malformation as recited by Applicants' claims. In addition, Thomson does not teach or suggest "a biodurable reticulated elastomeric matrix" as recited by Applicants' claims 27, 34, 52, 54, 55 and 65 and defined by the specification as:

> The biodurable elastomeric matrices forming the scaffold do not exhibit significant symptoms of breakdown, degradation, erosion or significant deterioration of mechanical properties relevant to their use when exposed to biological environments and/or bodily stresses for periods of time commensurate with the use of the implantable device such as controlled release or elution of pharmaceutically-active agents, e.g., a drug, or other biologically useful materials over a period of time. In one embodiment, the desired period of exposure is to be understood to be at least 29 days." (Specification, page 29, lines 12-24).

Thomson describes that "[t]he hydrophobic polyurethane foam scaffold is typically a reticulated foam made from water insoluable polyester or polyether backbones and diisocyanates as caps to the polyols." (Thomson, [0069]). One of ordinary skill in the art would understand that the polyurethane foams made from polyester or polyether backbones, as described by Thomson, are susceptible to degradation when exposed to biological environments and would not form a biodurable reticulated elastomeric matrix. For example, in the Abstract of a paper by Schuber et al. published in 1997, the authors acknowledge that "[i]t is generally accepted that

biodegradation of poly(ether-urethane) [sic] (PEUU) involves oxidation of the polyether segments on the surface where leukocytes are adhered." Schuber et al., "Role of oxygen in biodegradation of poly(etherurethane urea) elastomers," Journal of Biomedical Materials Research, Vol. 34, 519-530 (1997)(Exhibit A). As another example, a paper by Stokes et al. published in 1995 recognized that "[p]olyester polyurethanes, such as those used until only recently as coverings for implanted breast prostheses are subject to hydrolytic degradation." Stokes et al., "Polyurethane Elastomer Biostability," Journal of Biomaterials Applications, Vol. 9, 321-354, 350 (1995)(Exhibit B).

Spaans discloses a biomedical polyurethane based on diisocyanate linked polyester polymer and diol components, said diol component having a uniform block length. Spaans does not teach or suggest either a device for treating a vascular malformation or a reticulated elastomeric matrix as recited by Applicants' claims.

For at least the reasons discussed above, Applicants respectfully submit that Gilson in view of Thomson and/or Spaans do not teach or suggest Applicant's invention as recited by claims 26-30, 32-43, 50-58 and 63-67 . Therefore, Applicants respectfully request withdrawal of all §103 rejections.

CONCLUSION

Based on the foregoing remarks, Applicants respectfully request withdrawal of the rejections of claims and allowance of this application. In the event that a telephone conference would assist in the examination of this application, Applicants invite the Examiner to contact the undersigned at the number provided.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-3732**, Order No. 14596.105002. In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-3732**, Order No. 13566.105016.

Respectfully submitted,
King & Spalding, LLP

Dated: September 13, 2007

By: _____
Scott T. Weingaertner
Registration No. 37,756

Customer Number 65989
Correspondence Address:
King & Spalding
1185 Avenue of the Americas
New York, NY 10036-4003
(212) 556-2227 Telephone
(212) 556-2222 Facsimile